

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C. 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 11 January 2000 (11.01.00)	
International application No. PCT/GB99/01571	Applicant's or agent's file reference SMW/BP5777081
International filing date (day/month/year) 17 May 1999 (17.05.99)	Priority date (day/month/year) 15 May 1998 (15.05.98)
Applicant KOUZARIDES, Tony	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

01 December 1999 (01.12.99)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No.: (41-22) 740.14.35</p>	<p>Authorized officer</p> <p>S. Mafla</p> <p>Telephone No.: (41-22) 338.83.38</p>
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New National Phase Patent Application of PCT/GB99/012571

Atty: Mary J. Wilson

Serial No.: (To Be Assigned)

Date: Nov. 15, 2000

Inventor/s: KOUZARIDES

C#/M#: 620-118

Title: ASSAYS, METHODS AND MEANS FOR
MODULATING E2F ACTIVITY

X Preliminary Amendment
X PTO-1449
X International Search Report
\$ 2102 Fee (Check)
Other: Transmittal Letter (x2)

09/700417

525 Rec'd PCT/PTC 15 NOV 2000

PCT/GB 99/01571

Different

PCT/GB 99/012571

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 99/01571

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G01N33/68 C07K14/47

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 G01N C07K C12Q C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 03652 A (US HEALTH ;HOWARD BRUCE H (US); NAKATANI YOSHIHIRO (US)) 29 January 1998 (1998-01-29) claims 5,15,16	15,17-23
X	WO 97 35975 A (CANCER RES CAMPAIGN TECH ;KOUZARIDES TONY (GB); HAGEMEI ER CHRISTIA) 2 October 1997 (1997-10-02) claim 43	15-32
A	WO 97 35990 A (JAMISON TIMOTHY F ;HARVARD COLLEGE (US); TAUNTON JACK (US); HASSIG) 2 October 1997 (1997-10-02) the whole document	1-23
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

*** Special categories of cited documents :**

- * "A" document defining the general state of the art which is not considered to be of particular relevance
- * "E" earlier document but published on or after the international filing date
- * "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- * "O" document referring to an oral disclosure, use, exhibition or other means
- * "P" document published prior to the international filing date but later than the priority date claimed

* "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

* "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

* "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

* "&" document member of the same patent family

Date of the actual completion of the international search

1 October 1999

Date of mailing of the international search report

11/10/1999

Name and mailing address of the ISA

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Authorized officer

Hoekstra, S

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 99/01571

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>BANDARA L R ET AL: "FUNCTIONAL SYNERGY BETWEEN DP-1 AND E2F-1 IN THE CELL CYCLE-REGULATING TRANSCRIPTION FACTOR DRTF1/E2F" EMBO JOURNAL, vol. 12, no. 11, 1 January 1993 (1993-01-01), pages 4317-4324, XP002061240 ISSN: 0261-4189 the whole document</p>	1-23
A	<p>ADAMS P D ET AL: "TRANSCRIPTIONAL CONTROL BY E2F" SEMINARS IN CANCER BIOLOGY, vol. 6, no. 2, 1 April 1995 (1995-04-01), pages 99-108, XP000601456 ISSN: 1044-579X the whole document</p>	1-23
A	<p>YANG X -J ET AL: "A P300/CBP-ASSOCIATED FACTOR THAT COMPETES WITH THE ADENOVIRAL ONCOPROTEIN E1A" NATURE, vol. 382, no. 8589, 25 July 1996 (1996-07-25), pages 319-324, XP002050400 ISSN: 0028-0836 cited in the application the whole document</p>	1-23
A	<p>LAM EWF ET AL: "An E2F-binding site mediates cell-cycle regulated repression of mouse B-myb transcription" EMBO JOURNAL, vol. 7, no. 12, 1 January 1993 (1993-01-01), page 2705 2713 XP002078852 ISSN: 0261-4189 the whole document</p>	1-23

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SMW/BP5777081		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB99/01571	International filing date (day/month/year) 17/05/1999	Priority date (day/month/year) 15/05/1998	
International Patent Classification (IPC) or national classification and IPC G01N33/68			
Applicant CANCER RESEARCH CAMPAIGN TECHNOLOGY LIMITED et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 01/12/1999	Date of completion of this report 12.05.00
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Hoekstra, S Telephone No. +31 70 340 2847 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB99/01571

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-69 as originally filed

Claims, No.:

1-23 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 21-23.

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB99/01571

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 21-23.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-20
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-14
	No:	Claims	15-20 <u>103</u>
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Claims 1-14 are limited to methods for identifying agents that affect acetylation of transcription factor E2F. In particular acetylation by P/CAF.

The closest prior art is considered to be Adams et al. which discusses transcriptional control by E2F. The contribution to the state of the art made by the present application is the novel teaching that E2F is regulated, at least in part, by way of acetylation of specified Lysine sites in particular through P/CAF.

Claims 1-14 are all limited to at least one process step which is based on this teaching ("determining acetylation of E2F polypeptide or peptide"). These claims relate to novel matter only which could not be arrived at in an obvious manner since none of the documents cited in the search report discloses or suggests that E2F is regulatable via acetylation. Moreover, only histone proteins have hitherto been recognised as substrates for the acetylating activity of P/CAF. Documents mentioning both E2F and P/CAF never suggest that the known acetylation activity of P/CAF uses E2F as substrate.

Claims 1-14 are hence considered to meet the requirements of Article 33(2) and (3) PCT.

Claims 15-20 relate to peptides, their encoding nucleic acids and their first and second medical uses. The peptides claimed are considered novel in view of their size limitation but follow in their general and broad outline in an obvious manner from documents disclosing P/CAF or E2F independently (Yang et al. and WO9803652). It should be noted that the functional definition is not supported in the claim by structural features. In consequence inventive peptides, if any, are accompanied in the claim by many more obvious peptides. The inclusion of obvious peptides renders the claim non-compliant with Article 33(3) PCT.

Re Item VIII

Certain observations on the international application

The independent claims comprise several alternatives which would better be defined in

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB99/01571

alternative independent claims. The presently drafted claims are considered not concise and therefor unclear (Article 6 PCT).

Claim 12 is identified as an independent claim as it relates to the medical use of an "agent" and is not limited to the process steps of the claims it refers to.

Claim 12 is further recognised as a method of treatment for which this IPEA is not required to carry out a preliminary examination.

It is nevertheless considered that the claim relates to an agent which is only characterised by the way it has been identified. This contravenes the requirements of Article 6 PCT because it cannot be established what the subject-matter is for which protection is sought.

Claims 15-20 lack essential features of the invention (Rule 6.3(a) PCT).

Also present claims 21-23 relate to agents defined by reference to the way they have been detected.

These claims cover all products being so detected and having the desired property of affecting E2F acetylation, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such products.

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WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : G01N 33/68, C07K 14/47	A1	(11) International Publication Number: WO 99/60407 (43) International Publication Date: 25 November 1999 (25.11.99)
(21) International Application Number: PCT/GB99/01571 (22) International Filing Date: 17 May 1999 (17.05.99) (30) Priority Data: 9810562.0 15 May 1998 (15.05.98) GB (71) Applicant (for all designated States except US): CANCER RESEARCH CAMPAIGN TECHNOLOGY LIMITED [GB/GB]; 6-10 Cambridge Terrace, Regent's Park, London NW1 4JL (GB). (72) Inventor; and (75) Inventor/Applicant (for US only): KOUZARIDES, Tony [GB/GB]; Wellcome/CRC Institute, Tennis Court Road, Cambridge CB2 1QR (GB). (74) Agents: WALTON, Seán, M. et al.; Mewburn Ellis, York House, 23 Kingsway, London WC2B 6HP (GB).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: ASSAYS, METHODS AND MEANS FOR MODULATING E2F ACTIVITY		
(57) Abstract <p>P/CAF interacts with and acetylates E2F, this acetylation affecting ability of E2F to stimulate transcription. Interaction between P/CAF and E2F and acetylation of E2F by P/CAF are modulated, affecting ability of E2F to stimulate transcription, induction of S-phase in cells, oncogenicity of cells, and induction of apoptosis in cells. Agents are obtained for treatment of disorders of cell growth.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 99/01571

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G01N33/68 C07K14/47

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G01N C07K C12Q C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 03652 A (US HEALTH ;HOWARD BRUCE H (US); NAKATANI YOSHIHIRO (US)) 29 January 1998 (1998-01-29) claims 5,15,16 ---	15,17-23
X	WO 97 35975 A (CANCER RES CAMPAIGN TECH ;KOUZARIDES TONY (GB); HAGEMEI ER CHRISTIA) 2 October 1997 (1997-10-02) claim 43 ---	15-32
A	WO 97 35990 A (JAMISON TIMOTHY F ;HARVARD COLLEGE (US); TAUNTON JACK (US); HASSIG) 2 October 1997 (1997-10-02) the whole document --- -/-	1-23

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

*** Special categories of cited documents :**

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

1 October 1999

Date of mailing of the international search report

11/10/1999

Name and mailing address of the ISA

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Authorized officer

Hoekstra, S

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 99/01571

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>BANDARA L R ET AL: "FUNCTIONAL SYNERGY BETWEEN DP-1 AND E2F-1 IN THE CELL CYCLE-REGULATING TRANSCRIPTION FACTOR DRTF1/E2F" EMBO JOURNAL, vol. 12, no. 11, 1 January 1993 (1993-01-01), pages 4317-4324, XP002061240 ISSN: 0261-4189 the whole document</p> <p style="text-align: center;">---</p>	1-23
A	<p>ADAMS P D ET AL: "TRANSCRIPTIONAL CONTROL BY E2F" SEMINARS IN CANCER BIOLOGY, vol. 6, no. 2, 1 April 1995 (1995-04-01), pages 99-108, XP000601456 ISSN: 1044-579X the whole document</p> <p style="text-align: center;">---</p>	1-23
A	<p>YANG X -J ET AL: "A P300/CBP-ASSOCIATED FACTOR THAT COMPETES WITH THE ADENOVIRAL ONCOPROTEIN E1A" NATURE, vol. 382, no. 8589, 25 July 1996 (1996-07-25), pages 319-324, XP002050400 ISSN: 0028-0836 cited in the application the whole document</p> <p style="text-align: center;">---</p>	1-23
A	<p>LAM EWF ET AL: "An E2F-binding site mediates cell-cycle regulated repression of mouse B-myb transcription" EMBO JOURNAL, vol. 7, no. 12, 1 January 1993 (1993-01-01), page 2705 2713 XP002078852 ISSN: 0261-4189 the whole document</p> <p style="text-align: center;">-----</p>	1-23

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 99/01571

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 21-23
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 21-23

Present claims 21-23 relate to agents defined by reference to the way they have been detected.

The claims cover all products being so detected and having the desired property of affecting E2F accetylation, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such products. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the product by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the products being derived from E2F and/or P/CAF (i.e. peptides).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 99/01571

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9803652	A	29-01-1998	AU	4043897 A	10-02-1998
WO 9735975	A	02-10-1997	AU	2168097 A	17-10-1997
WO 9735990	A	02-10-1997	AU	2990597 A	17-10-1997